DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Amendment filed 29 September 2011 has been entered in full. Claims 1-3, 5, and 6 have been amended, and claims 7-9 have been added. Newly added claims 7-9 will be examined as they fit under the rubric of the elected invention. Therefore, claims 1-9 are currently pending and the subject of this Office action.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections and/or Rejections

3. The objection to claims 5 and 6 as set forth at pg. 2 of the previous Office action (mailed 31 March 2011) is withdrawn in view of Applicant's amendment (filed 29 September 2011).

4. The rejection of claims 1-4 under 35 U.S.C. § 101 as set forth at pg. 2 of the previous Office action (mailed 31 March 2011) is withdrawn in view of Applicant's persuasive arguments (filed 29 September 2011).

5. The rejection of claims 1-4 under 35 U.S.C. § 112, second paragraph, as set forth at pg. 32 of the previous Office action (mailed 31 March 2011) is withdrawn in view of Applicant's amendment of claims 1-3 (filed 29 September 2011).

Maintained and/or New Objections and/or Rejections

Claim Rejections - 35 USC § 112, 2nd Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 3 is rejected as being indefinite because it is unclear what is meant by the phrase "corresponds to amino acids 1-448 of an amino acid sequence set forth in SEQ ID NO:1" in line 3 of the claim, and "corresponds to amino acids 1-447 of SEQ ID NO:1" in line 5 of the claim. Without knowing whether the limitation refers to a polypeptide consisting of the amino acid sequence of SEQ ID NO:1, a polypeptide comprising the amino acid sequence of SEQ ID NO:1, or a polypeptide that is similar to SEQ ID NO:1 (and to what degree, structurally and/or functionally), the metes and bounds of the claim cannot be determined.

Claim Rejections - 35 USC § 112, 1st Paragraph (Written Description)

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

11. The claims are drawn very broadly to an antibody subtype of the humanized PM-1 antibody against interleukin-6 receptor (IL-6R) and in which one (subtype 1) or both (subtype 2) C-terminal(s) of the heavy chain is Pro-NH_2. The claims also recite wherein the heavy chain of the native humanized PM-1 antibody corresponding to the subtype has a heavy chain that corresponds to amino acids 1-448 of an amino acid sequence set forth in SEQ ID NO:1, and a heavy chain of the subtype antibody having the C-terminal Pro- NH_2 corresponds to amino acids 1-447 of SEQ ID NO:1. The claims also recite pharmaceutical compositions comprising the same. Thus, the claims are drawn to a genus of polynucleotide molecules that are defined only by a name (i.e., PM-1) or a partial structure.

12. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a partial structure in the form of a recitation of "humanized PM-1 antibody against interleukin-6 receptor (IL-6R) and in which one (subtype 1) or both (subtype 2) C-terminal(s) of the heavy chain is Pro-NH_2.". There is no identification of any particular structure of the "humanized PM-1 antibody". While the specification provides adequate written description for a humanized PM-1 antibody having a heavy chain comprising the amino acid sequence of SEQ ID NO:1 and a light chain comprising the amino acid sequence of SEQ ID NO:2, and subtypes of

said antibody in which one (subtype 1) or both (subtype 2) C-terminal(s) of the heavy chain is Pro-NH_2 at position 447 of SEQ ID NO:1, it does not provide adequate written description for a commensurate number of the species of antibodies encompassed by the claims. The distinguishing characteristics of the claimed genus are not described. The only adequately described species are (1) an antibody subtype of the humanized PM-1 antibody having a heavy chain comprising the amino acid sequence of SEQ ID NO:1 and a light chain comprising the amino acid sequence of SEQ ID NO:2, wherein the C-terminal of the heavy chain of the subtype is Pro-NH_2 at position 447 of SEQ ID NO:1, and (2) an antibody subtype of the humanized PM-1 antibody having a heavy chain comprising the amino acid sequence of SEQ ID NO:1 and a light chain comprising the amino acid sequence of SEQ ID NO:2, wherein the C-terminal of both heavy chains of the subtype is Pro-NH_2 at position 447 of SEQ ID NO:1. Accordingly, the specification does not provide adequate written description of the claimed genus.

13. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed"* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

14. With the exception of the antibodies referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that

it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

15. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

16. Therefore, only the antibodies referred to above, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Summary

17. No claim is allowed.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Jeffrey Stucker**, can be reached on **(571) 272-0911**. The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. L./
Examiner, Art Unit 1647
November 29, 2011

/Christine J Saoud/
Primary Examiner, Art Unit 1647